510(k) SUMMARY

Freedom Sciences LLC
Version 1.5 Motion Control Module

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Freedom Sciences, LLC
The Navy Yard - Quarters M2
4601 South Broad Street
Philadelphia, PA 19112

Contact Person: Edward A. Kroll
Representative Consultant for
Freedom Sciences, LLC

Date Prepared: June 8, 2009

Name of Device and Name/Address of Sponsor

Freedom Sciences Version Motion 1.5 Control Module (MCM)

Freedom Sciences, LLC
The Navy Yard - Quarters M2
4601 South Broad Street
Philadelphia, PA 19112

Common or Usual Name

Power Wheelchair

Classification Name

Wheelchair, Powered

Predicate Devices

Freedom Sciences LLC Motion Control Module for Powered Wheelchairs (K073330)

Intended Use

The intended use of the Freedom Sciences Version 1.5 Motion Control Module is to allow for remote motion control of a powered wheelchair that uses the Invacare MK6 Electronics while the wheelchair is unoccupied. It is not intended for use when a person is seated in the wheelchair.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Freedom Sciences Version 1.5 Motion Control Module for powered wheelchairs is a wireless, remote control product designed for use with powered wheelchairs which use the Invacare MK6 Electronics . Its intended function and use is to allow for remote motion control of the powered wheelchair only while the wheelchair is unoccupied. It is not intended for use when a person is seated in the wheelchair.

The MCM v1.5 allows for remote motion control using high level motion control commands. It interfaces to the power wheelchair using the host wheelchair attendant control interface on the motor controller. This method of interfacing with the powered wheelchair retains all configured safety interlocks inherent to the host motor controller itself and is the standard means for integrating auxiliary input devices.

B. Substantial Equivalence

The Freedom Sciences MCM v1.5 Motion Control Module is substantially equivalent to the Freedom Sciences Motion Control Module (MCM) for powered wheelchairs (K073330).

Performance Data

The MCM v1.5 was tested as required by FDA's July 26, 1995, draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three- Wheeled Vehicles". The Freedom Sciences MCM v1.5 met the applicable required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2009

Freedom Sciences, LLC
% Spectre Solutions, Incorporation
Mr. Edward A. Kroll
President
5905 Fawn Lane
Cleveland, Ohio 44141

Re: K091723
Trade/Device Name: Freedom Sciences, LLC Version 1.5. Motion Control Module (MCM)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: June 8, 2009
Received: June 11, 2009

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Freedom Sciences, LLC Version 1.5 Motion Control Module (MCM)

Indications for Use:

The intended use of the Freedom Sciences version 1.5 Motion Control Module is to allow for remote motion control of a powered wheelchairs while the wheelchair is unoccupied. It is not intended for use when a person is seated in the wheelchair.

The MCM Version 1.5 is compatible with powered wheelchairs that use Invacare MK6 Electronics.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091723